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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/547,843 | 09/06/2005 | Takashi Horiguchi | Q101074 | 9679 |

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| EXAMINER | |
|---|---|
| CHERNYSHEV, OLGA N | |
| **ART UNIT** | **PAPER NUMBER** |
| 1649 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 10/10/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/547,843 | HORIGUCHI ET AL. | |
| | Examiner | Art Unit | |
| | Olga N. Chernyshev | 1649 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,4-7,10,17 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,10,17 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/13/7*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. Claims 1, 2, 4, 6, 7, 10 and 17 have been amended and claims 3, 8-9, 11-16, 18-25 and 27-36 have been cancelled as requested in the amendment filed on August 13, 2007. Following the amendment, claims 1, 2, 4-7, 10, 17 and 26 are pending in the instant application.

Claims 1, 2, 4-7, 10, 17 and 26 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on August 13, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### *Claim Rejections - 35 USC § 101*

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 2, 4-7, 10, 17 and 26 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record in section 5 of Paper mailed on May 11, 2007. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant traverses the rejection on premises that "the presently claimed protein [C1] has a cell-death promoting activity (Example 4), and an inhibitory activity on secretion of Aβ40 and Aβ42 (Example 5)" (pp. 6-7 of the Response). Applicant further refers to the prior art articles showing "an important role of endoplasmic reticulum stress response in various neurodegenerative diseases including Alzheimer's disease" and concludes that , "those skilled in the art would readily understand that an agent that promotes cell death and inhibits secretion of amyloid β-proteins can be used for treatment of neurodegenerative diseases such as Alzheimer's disease" (p. 7 of the Response). Applicant's arguments have been fully considered but are not persuasive for the following reasons.

Example 4, p. 69 of the instant specification demonstrates that cells transfected with C1 gene had slightly increased survival rate as compared to control cells (see Figures 1 and 2). The specification does not disclose the statistical significance of these data or comparison to control cells transfected with a different gene, therefore, it appears that no conclusion could be made regarding involvement of C1 gene in apoptosis, as asserted by Applicant. Further, the specification fails to present any scientific reasoning as how this data support the role of C1 protein in Alzheimer's disease.

Example 5, p. 69 of the instant specification describes results of experiments, in which two groups of cells, transformed with C1 gene and transformed with GFP gene, were examined for spontaneous Aβ secretion in culture. It is stated that the cells transfected with C1 gene secreted less Aβ than the cells transfected with GFP. Since there is no control data regarding spontaneous secretion of Aβ from the wild-type cells, the statement that C1 has "an inhibitory activity" appears to be not fully supported by the evidence presented by Applicant. The

specification also fails to explain how spontaneous secretion of Aβ in cells transfected with C1 relates to etiology of Alzheimer's disease in particular and neurodegenerative diseases in general. According to the knowledge in the art, neurodegenerative diseases do not have common etiology, symptomology or common course of development. Moreover, only a few neurodegenerative diseases, Alzheimer's disease included, have amyloid (Aβ) as a recognized pathological factor. Thus, it is unclear how a protein, of which no biological role or relevance to a specific physiological process or clinical condition is known, could have a specific significance during neurodegeneration.

The articles by Sai et al., Unterberger et al., Imaizumi et al., and Imai et al. submitted with Applicant's response have been fully considered. However, the Examiner fails to find a specific connection between the cited art and the instant currently claimed polypeptide C1 of SEQ ID NO: 1. It is noted that none of the articles specifically address the significance of the experimental model used by Applicant with respect to Alzheimer's disease, for example, or provided any support or further explained the relevance of findings presented in the instant specification to neurodegenerative pathology of the brain. The Examiner maintains that since the instant specification does not disclose a credible "real world" use for the encoded protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. *See In re Fisher,* 2005 WL 2139421 (Sept. 7, 2005). The *Fisher* court interpreted *Brenner v. Manson,* 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility" 2005 WL 2139421, at *4. The *Fisher* court held that §

101 requires a utility that is both substantial and specific. *Id.* At *5. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *Id.*

The court held that a specific utility is "a use which is not so vague as to be meaningless." *Id.* In other words, "in addition to providing a 'substantial' utility, an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.*

Just as in *Fisher* case where the Board reasoned that use of the claimed ESTs for the identification of polymorphisms is not a specific and substantial utility because "[w]ithout knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage," (*Id.*, slip op. at 15), in the instant case Applicant's asserted utility for the polypeptide of SEQ ID NO: 1, particularly in view of a lack of knowledge as to the biological function of the polypeptide of SEQ ID NO: 1 or its relevance to Alzheimer's disease, constitutes a utility that requires further research to identify or reasonably confirm a "real world" context of use.

For reasons of record fully explained earlier and reasons above, the instant rejection is maintained.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2, 4-7, 10, 17 and 26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Conclusion***

8. No claim is allowed.

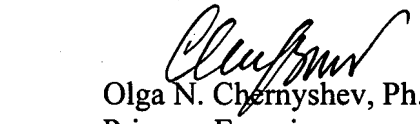
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

October 5, 2007